

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

NOVO NORDISK INC. and	)	
NOVO NORDISK A/S,	)	
Plaintiffs,	)	Civil Action No. 10-cv-03750-PGG
	)	
v.	)	
	)	<b>LUPIN LTD.'S ANSWER, SEPARATE</b>
LUPIN LTD.,	)	<b>DEFENSES AND COUNTERCLAIMS TO</b>
	)	<b>PLAINTIFFS' COMPLAINT</b>
Defendant.	)	
	)	<b>(Filed Electronically)</b>

Defendant Lupin Ltd. ("Defendant" or "Lupin") hereby answers the Complaint of Plaintiffs Novo Nordisk Inc. and Novo Nordisk A/S (collectively, "Plaintiffs") – for which every allegation not expressly admitted is denied – as follows:

**NATURE OF THE ACTION**

1. This is a civil action for the infringement of United States Patent No. 6,677,358 pursuant to the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

**ANSWER:** Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer is required, Lupin admits that the Complaint purports to allege infringement of United States Patent No. 6,677,358 ("the '358 patent"). Lupin denies all remaining allegations in Paragraph 1.

**THE PARTIES**

2. Plaintiff Novo Nordisk Inc. is a Delaware corporation, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

**ANSWER:** On information and belief, Lupin admits the allegations in Paragraph 2.

3. Plaintiff Novo Nordisk A/S is a corporation organized and existing under the laws of the Kingdom of Denmark, and has its principal place of business at Novo Allé, 2880 Bagsværd, Denmark.

**ANSWER:** On information and belief, Lupin admits the allegations in Paragraph 3.

4. Upon information and belief, Lupin is an alien corporation organized and existing under the laws of the Sovereign Nation of India, having a principal place of business at Laxmi Towers, "B" Wing, 5<sup>th</sup> Floor, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India. Lupin Limited develops and manufactures prescription pharmaceutical drugs, including generic drug products.

**ANSWER:** Lupin admits that Lupin Ltd. is an Indian corporation located solely in India, that Lupin Ltd. has a place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051, India, and that Lupin Ltd. develops and manufactures pharmaceutical drug products. Lupin denies all remaining allegations in Paragraph 4.

#### **JURISDICTION AND VENUE**

5. This action arises under the patent laws of the United States. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, and 35 U.S.C. § 271.

**ANSWER:** Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that the Complaint purports to allege patent infringement, and that subject matter jurisdiction is proper for claims asserted against Lupin Ltd. under 35 U.S.C. § 271(e)(2)(A) only. Lupin denies all remaining allegations in Paragraph 5.

6. Personal jurisdiction over Lupin in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a), and because, *inter alia*, Lupin manufactures pharmaceuticals and pharmaceutical products that are sold and used throughout the United States, including within New York; Lupin regularly, systematically, and currently transacts business in the Southern District of New York, at least by making and shipping into this Judicial District, or by using, offering to sell, or selling, or by causing others to use, offer to sell, or sell, pharmaceutical products in this Judicial District; and Lupin derives substantial revenue from goods used or consumed or services rendered in New York, including in this Judicial District. Furthermore, Lupin's submission of ANDA No. 200-624, discussed below, indicates its intention to engage in the commercial manufacture, use, or

sale of products that will compete directly with Novo Nordisk's PRANDIMET<sup>®</sup>, of which a significant portion of sales occur in the State of New York and this judicial district.

**ANSWER:** Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Lupin does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Lupin denies all remaining allegations in Paragraph 6.

7. Venue is proper in this Judicial District pursuant to at least 28 U.S.C. §§ 1391 and 1400(b).

**ANSWER:** Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent that an answer is required, denied. Further answering, solely to conserve the resources of the parties and the Court, Lupin does not contest venue solely for the limited purposes of this action only.

#### **GENERAL BACKGROUND**

8. Type 2 diabetes mellitus, also known as non-insulin dependent diabetes mellitus ("NIDDM"), is the most common form of diabetes, and affects millions of children and adults throughout the world. It is a chronic disorder characterized by hyperglycemia-elevated blood glucose levels in the body—typically as a result of insufficient insulin production in the pancreas, excessive glucose production in the liver, or a resistance to the effects of insulin at the cellular level. Hyperglycemia inhibits the normal functioning of the body's cells, and if left uncontrolled, can severely damage the kidneys, eyes, nervous system, heart, and blood vessels. As a result, type 2 diabetes is among the leading causes of death in the United States.

**ANSWER:** Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8, and therefore denies these allegations.

9. Founded in 1923, Novo Nordisk has pioneered many key breakthroughs in diabetes treatment, and spends well in excess of \$1 billion annually on research and development in the field of diabetes care. Up until the mid-1990s, type 2 diabetic patients were generally treated with monotherapy, *i.e.*, a single oral antidiabetic drug (“OAD”). At the time, combination therapy the treatment of diabetes with two or more OADs—was not the standard of care and was, in fact, quite rare.

**ANSWER:** Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, denied.

10. Following a clinical trial commenced in Australia in 1995 that produced unexpected and surprising results, Novo Nordisk pursued patent protection in 1997 relating to an important breakthrough in the treatment of type 2 diabetes: combination therapy with repaglinide and metformin. On January 13, 2004, United States Patent No. 6,677,358, entitled “NIDDM Regimen,” (“the ‘358 patent”) was duly and legally issued by the United States Patent and Trademark Office to Novo Nordisk A/S as assignee. Novo Nordisk A/S has at all times been, and continues to be, the sole owner of the ‘358 patent. A copy of the ‘358 patent is attached hereto and incorporated herein by reference as Exhibit A.

**ANSWER:** Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that the electronic records of the United States Patent and Trademark Office list the title of the ‘358 patent as “NIDDM Regimen.” Lupin also admits that the cover page of the ‘358 patent identifies “Novo Nordisk A/S” as the purported “assignee.” Lupin also admits that what purports to be a copy of the ‘358 patent is attached to the Complaint as Exhibit A. Lupin expressly denies that the ‘358 patent was “duly and legally issued,” and further denies all remaining allegations in Paragraph 10.

11. In May 2008, Novo Nordisk Inc. filed New Drug Application (“NDA”) 22-386 with the Food and Drug Administration (“FDA”), seeking approval for the sale of repaglinide-metformin HCl combination tablets. In June 2008, the FDA approved that NDA. Novo Nordisk Inc. holds the approved NDA.

**ANSWER:** Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Lupin admits that the electronic version of the U.S. Food and Drug Administration’s (“FDA”) publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* (commonly known as the “Orange Book”), identifies

“NOVO NORDISK INC” as the “applicant” for New Drug Application (“NDA”) No. 22-386 for Prandimet<sup>®</sup> (repaglinide-metformin HCl) tablets approved June 23, 2008. Lupin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 11, and therefore denies these allegations.

12. Since February 2009, Novo Nordisk has marketed PrandiMet<sup>®</sup>-brand repaglinide-metformin HCl combination tablets.

**ANSWER:** Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 12, and therefore denies these allegations.

13. PrandiMet<sup>®</sup> is approved for use as an adjunct to diet and exercise to improve glycemic control in patients with Type 2 diabetes mellitus (also called “non-insulin dependent diabetes mellitus, or “NIDDM”).

**ANSWER:** Lupin lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 13, and therefore denies these allegations.

14. The listing for PrandiMet<sup>®</sup> in the FDA’s “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly referred to as the “Orange Book”) includes the ‘358 patent.

**ANSWER:** Lupin admits that the electronic version of FDA’s Orange Book includes PrandiMet. Lupin further admits that the Orange Book lists the ‘358 patent in connection with PrandiMet. Lupin denies all remaining allegations in Paragraph 14.

15. Upon information and belief, Lupin is in the business of manufacturing, marketing, and distributing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies.

**ANSWER:** Lupin admits that it develops and manufactures pharmaceutical drug products, including quality generic medicines. Lupin denies all remaining allegations in Paragraph 15.

**COUNT I**  
**(Infringement of U.S. Patent No. 6,677,358)**

16. Novo Nordisk hereby realleges and incorporates by reference the allegations of paragraphs 1-15 of this Complaint.

**ANSWER:** Lupin restates and incorporates by reference its responses to the allegations in Paragraph 1 through 15 as though fully set forth herein.

17. Upon information and belief, Lupin filed Abbreviated New Drug Application (“ANDA”) No. 200-624 with the FDA under 21 U.S.C. § 355(j) seeking approval to market (i) tablets comprising a combination of 1 mg repaglinide and 500 mg metformin HCl and (ii) tablets comprising a combination of 2 mg repaglinide and 500 mg metformin HCl (collectively, the “Proposed Generic Products”).

**ANSWER:** Lupin admits that it has submitted an Abbreviated New Drug Application (“ANDA”) to FDA for metformin hydrochloride/repaglinide tablets, 500 mg/1 mg and 500 mg/2 mg. Lupin denies all remaining allegations in Paragraph 17.

18. By its ANDA filing, Lupin has indicated that it intends to engage, and there is a substantial likelihood that it will engage, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Proposed Generic Products, which Lupin has alleged will be bioequivalent to Novo Nordisk’s patented repaglinide-metformin combination drug products, immediately or imminently upon receiving FDA approval to do so.

**ANSWER:** Denied.

19. By its ANDA filing, Lupin seeks to obtain approval to manufacture, use, offer for sale, sell, and/or import the Proposed Generic Products, alleged equivalents of Novo Nordisk’s PRANDIMET® drug products, prior to the expiration date of the ‘358 patent.

**ANSWER:** Lupin admits that Lupin’s ANDA seeks FDA approval for metformin hydrochloride/repaglinide tablets, 500 mg/1 mg and 500 mg/2 mg, prior to expiration of the ‘358 patent. Lupin denies all remaining allegations in Paragraph 19.

20. By a letter dated March 22, 2010 (the "Notice Letter"), Lupin informed Novo Nordisk that it had filed a certification to the FDA pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV). On or about March 23, 2010, NDA holder Novo Nordisk Inc. received the Notice Letter. On or about March 24, 2010, patent owner Novo Nordisk A/S received the Notice Letter.

**ANSWER:** Lupin admits that, in a letter dated March 22, 2010, Lupin provided Novo Nordisk Inc. and Novo Nordisk A/S with the requisite notice of Lupin's ANDA, which contains a "paragraph IV certification," and that Lupin's notice satisfies all statutory and regulatory requirements. Lupin lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 20, and therefore denies these allegations.

21. The Notice Letter, purporting to be Lupin's Notice of Certification under 21 U.S.C. § 355(j)(2)(B)(iv), alleges that, in Lupin's opinion, the '358 patent is invalid, unenforceable, and/or will not be infringed by the Proposed Generic Products.

**ANSWER:** Lupin admits that its Notice Letter provides, *inter alia*, the detailed legal and factual bases for Lupin's "paragraph IV certification," stating that, in Lupin's opinion and to the best of its knowledge, the '358 patent is invalid, unenforceable and/or not infringed.

22. Lupin's filing of ANDA No. 200-624 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of drug products containing repaglinide and metformin, or salts thereof, before the expiration of the '358 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

23. Lupin's generic metformin hydrochloride/repaglinide tablets, 500 mg/1 mg and 500 mg/2 mg, will and are intended to compete directly with Novo Nordisk's PRANDIMET<sup>®</sup> (metformin hydrochloride/repaglinide) 500 mg/1 mg and 500 mg/2 mg, respectively.

**ANSWER:** Denied.

24. Upon information and belief, upon approval of ANDA No. 200-624, Lupin will directly and/or indirectly infringe the '358 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

**ANSWER:** Denied.

25. The acts of infringement set forth above will cause Novo Nordisk irreparable harm for which it has no adequate remedy at law, and will continue unless the FDA's approval of ANDA No. 200-624 is stayed until the expiration of the '358 patent, and unless Lupin is preliminarily and permanently enjoined by this Court.

**ANSWER:** Denied.

\* \* \*

Lupin denies all allegations and statements not expressly admitted or responded to herein. Lupin further denies that Plaintiffs are entitled to any of the relief requested, or to any relief at all, and respectfully requests that the Court:

- a. dismiss this action with prejudice;
- b. enter judgment in favor of Lupin;
- c. award Lupin its reasonable attorneys' fees and the costs of defending this action and prosecuting its counterclaims according to 35 U.S.C. § 285; and
- d. award Lupin such other and further relief as the Court deems just and appropriate.

### **SEPARATE DEFENSES**

Without prejudice to the denials set forth in the Answer, without admitting any allegation or statement in the complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Lupin asserts the following separate defenses:

#### **First Defense**

The Complaint fails to state a claim upon which relief may be granted.

#### **Second Defense**

This Court lacks subject matter jurisdiction over any claims asserted under 35 U.S.C. § 271(a), (b) and/or (c).

### **Third Defense**

This Court lacks subject matter jurisdiction because there is no case or controversy as to invalid and/or unenforceable patent claims.

### **Fourth Defense**

The manufacture, use, sale, offer for sale, or importation of the metformin hydrochloride/repaglinide product that is the subject of Lupin's ANDA has not infringed, does not infringe, and would not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and/or enforceable claim of the '358 patent, either literally or under the doctrine of equivalents.

### **Fifth Defense**

Lupin has not induced, does not induce, and will not induce infringement of any valid and/or enforceable claim of the '358 patent.

### **Sixth Defense**

Lupin has not contributed, does not contribute, and will not contribute to infringement of any valid and/or enforceable claim of the '358 patent.

### **Seventh Defense**

The claims of the '358 patents are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

### **Eighth Defense**

The Complaint fails to state a claim for an exceptional case and/or a claim for willful infringement.

### **Ninth Defense**

Any additional defenses or counterclaims that discovery may reveal, including but not limited to defenses of unenforceability.

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### **COUNTERCLAIMS**

Defendant/Counterclaim-Plaintiff Lupin Ltd. asserts the following counterclaims against Plaintiffs/Counterclaim-Defendants Novo Nordisk Inc. and Novo Nordisk A/S.

#### **Parties**

1. Lupin Ltd. is a corporation organized and existing under the laws of the Republic of India.
2. On information and belief, Novo Nordisk Inc. purports to be a corporation organized and existing under the laws of Delaware, also having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.
3. On information and belief, Novo Nordisk A/S purports to be a corporation organized and existing under the laws of the Kingdom of Denmark, with a principal place of business at Novo Allé, 2880 Bagsværd, Denmark.

#### **Jurisdiction and Venue**

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.
5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).
6. This Court has personal jurisdiction over the Plaintiffs/Counterclaim-Defendants because they have availed themselves of the rights and privileges of this forum by suing Lupin in

this District, and because they conduct substantial business in, and have regular and systematic contacts with, this District.

7. Venue is proper in this District under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

**Patents-in-Suit**

8. On or about January 13, 2004, the United States Patent and Trademark Office issued U.S. Patent No. 6,677,358 (“the ‘358 patent”), entitled “NIDDM Regimen,” to Peter Giørtz Müller.

9. Novo Nordisk Inc. and Novo Nordisk A/S purport and claim to have ownership of, and the right to enforce, the ‘358 patent.

10. On or about May 6, 2010, Novo Nordisk Inc. and Novo Nordisk A/S sued Lupin in this District alleging infringement of the ‘358 patent.

**COUNT I  
(Declaratory Judgment of Non-Infringement of the ‘358 Patent)**

11. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

12. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding non-infringement of the ‘358 patent.

13. The manufacture, use, sale, offer for sale, or importation of the metformin hydrochloride/repaglinide product that is the subject of Lupin Ltd.’s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the ‘358 patent, either directly or indirectly.

14. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of the metformin hydrochloride/repaglinide product that is the subject of

Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '358 patent, either directly or indirectly.

**COUNT II**  
**(Declaratory Judgment of Invalidity of the '358 Patent)**

15. Lupin re-asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

16. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Plaintiffs/Counterclaim-Defendants regarding invalidity of the '358 patent.

17. The claims of the '358 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code.

18. Lupin is entitled to a judicial declaration that the claims of the '358 patent are invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Lupin respectfully prays for judgment in its favor and against Plaintiff/Counterclaim-Defendants:

- a. declaring that the manufacture, use, sale, offer for sale, or importation of the metformin hydrochloride/repaglinide product that is the subject of Lupin Ltd.'s ANDA has not infringed, does not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '358 patent, either directly or indirectly;
- b. declaring the claims of the '358 patents invalid;
- c. ordering that Plaintiffs/Counterclaim-Defendants' complaint be dismissed with prejudice and judgment entered in favor of Lupin;
- d. declaring this case exceptional and awarding Lupin reasonable attorney's fees and costs under 35 U.S.C. § 285; and
- e. awarding Lupin such other and further relief as the Court may deem just and proper.

**DEMAND FOR JURY TRIAL**

Lupin hereby demands a trial by jury on all issues so triable.

Dated: July 22, 2010

Respectfully submitted,

LUPIN LTD.

/s/ Steven M. Amundson

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*Counsel for Lupin Ltd.*

**CERTIFICATE OF SERVICE**


I hereby certify that on this 22nd day of July, 2010, I caused the foregoing **LUPIN LTD.'S ANSWER, SEPARATE DEFENSES AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT** to be served via email upon:

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